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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **January 15, 2021**



**Cardiff Oncology, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**001-35558**  
(Commission File Number)

**27-2004382**  
IRS Employer  
Identification No.)

**11055 Flintkote Avenue**  
**San Diego, CA 92121**  
(Address of principal executive offices)

Registrant's telephone number, including area code: **(858) 952-7570**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	CRDF	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01 Other Events.**

On January 15, 2021, Cardiff Oncology, Inc. (the “Company”) issued a press release announcing the presentation of data from its Phase 1b/2 study in KRAS-mutated metastatic colorectal cancer (mCRC) as part of the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI), and provided an additional data update from its mCRC clinical program and initial findings from its Expanded Access Program. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits.

99.1 [Press Release of Cardiff Oncology, Inc. dated January 15, 2021.](#)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 15, 2021

CARDIFF ONCOLOGY, INC.

By: /s/ Mark Erlander  
Mark Erlander  
Chief Executive Officer

## Cardiff Oncology Presents Data that Continues to Demonstrate the Clinical Benefit of Onvansertib in KRAS-Mutated mCRC and Initial Findings from its Expanded Access Program

- Of the 12 Phase 1b patients evaluable for efficacy as of the ASCO-GI data cut-off date (November 1, 2020), 5 (42%) achieved a partial response (PR) and 8 (67%) have shown a durable response ranging from 6.1 to 13.7 months
- Since the ASCO-GI data cut-off date, 2 additional Phase 1b patients have had their initial 8-week scan showing stable disease (SD) and both remain on treatment to-date
- Time to achieving a PR ranges from 2 to 6 months in patients on treatment
- The recommended Phase 2 dose (RP2D) of onvansertib has been established at 15mg/m<sup>2</sup> and the Phase 2 segment of the ongoing trial is open to full enrollment of 26 patients across 6 sites in the U.S.
- In the Expanded Access Program (EAP), 6 (66%) of the initial 9 patients treated have shown tumor shrinkage and remain on treatment to-date with durable responses lasting an average of 6 months; 5 different KRAS mutation subtypes are represented (G12A, G12C, G12V, G13D, A146T); all patients had received prior treatment with FOLFIRI
- Decreases in the KRAS mutational burden in patients after the first cycle of treatment have been predictive of subsequent tumor shrinkage in both the clinical trial and EAP

**SAN DIEGO (January 15, 2021) – Cardiff Oncology, Inc. (Nasdaq: CRDF)**, a clinical-stage biotechnology company developing new treatment options for cancer patients in indications with the greatest medical need, including KRAS-mutated colorectal cancer, castration-resistant prostate cancer and leukemia, today announced the presentation of data from its Phase 1b/2 study in KRAS-mutated metastatic colorectal cancer (mCRC) as part of the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI), and provided an additional data update from its mCRC clinical program and initial findings from its Expanded Access Program.

Enrollment of patients in the Phase 1b segment of the Phase 1b/2 KRAS-mutated mCRC trial is complete and the recommended Phase 2 dose (RP2D) of onvansertib has been confirmed at 15 mg/m<sup>2</sup>. The Phase 2 segment of the trial is open to full enrollment of approximately 26 patients across 6 trial sites: USC Norris Comprehensive Cancer Center, Mayo Clinic Cancer Centers (Arizona, Rochester, Jacksonville), Kansas University Medical Center and CARTI Cancer Center.

“The Phase 1b data show that a significant percentage of patients had tumor shrinkage, achieved clinical benefit and, importantly, that the response appears durable with two-thirds of the patients having been on treatment for at least six months,” said Daniel H. Ahn, D.O., lead investigator and medical oncologist, Mayo Clinic Cancer Center, Arizona. “This highlights the promise of onvansertib plus standard-of-care as an effective second-line treatment for patients with KRAS-mutated mCRC. We look forward to building on these promising data during the Phase 2 portion of the trial.”

Initial findings from Cardiff Oncology’s EAP for onvansertib in KRAS-mutated mCRC are similar to results from the Phase 1b trial. In the EAP, 6 (66%) of the first 9 patients treated have shown tumor shrinkage and remain on treatment to-date with durable responses lasting an average of

6 months. Additionally, 5 different KRAS mutation subtypes are represented (G12A, G12C, G12V, G13D, A146T) and all patients had received prior treatment with FOLFIRI. Importantly, decreases in the KRAS mutational burden after the first cycle of treatment have been predictive of subsequent tumor shrinkage.

“We are pleased with the continued advancement of our KRAS-mutated mCRC clinical study and are excited to initiate enrollment in the Phase 2 segment of this trial,” said Dr. Mark Erlander, chief executive officer of Cardiff Oncology. “Additionally, our EAP is being very well received by clinicians and patients who would otherwise not have access to onvansertib because they don’t meet the strict eligibility criteria for our trial. We are encouraged by the initial observations and, in particular, the duration of response we are seeing, which is consistent with the data from our clinical trial. Of note, the key difference in the patients enrolled in our EAP is that several had received and progressed on prior FOLFIRI-based treatment and with the addition of onvansertib we are seeing tumor shrinkage and durable stable disease.”

The Phase 1b data will be featured in a poster, *A phase Ib/II study of the polo-like kinase 1 (PLK1) inhibitor, onvansertib, in combination with FOLFIRI and bevacizumab for second-line treatment of patients with KRAS-mutated metastatic colorectal Cancer (mCRC)*, presented by Dr. Daniel Ahn and streamed virtually at ASCO-GI on January 15<sup>th</sup> from 8:00 am – 6:15 pm ET during the Trials in Progress Poster Session: Colorectal Cancer (Abstract TPS155).

### **Highlights from the Poster Presentation:**

#### *Efficacy:*

- Of the 12 evaluable patients as of the ASCO-GI data cut-off date, 5 (42%) achieved a partial response (PR); 4 patients had a confirmed PR; 1 patient went on to curative surgery; 1 patient with a non-confirmed PR went off study due to an unrelated event prior to their 16-week confirmatory scan
- Time to achieving a PR ranges from 2 to 6 months in patients on treatment
- 8 (67%) showed durable responses of >6 months with a range from 6.1 to 13.7 months

#### *Biomarker Analyses:*

- 10 of 12 patients had a KRAS variant detected by ddPCR at baseline (all had a KRAS mutation detected by NGS)
- Clinical responses were observed across different KRAS variants, including the 3 most common in CRC
- The greatest decreases in KRAS mutant allelic frequency (MAF) after 1 cycle of treatment were observed in patients achieving a PR (ranging from -78% to -100%), while the 2 patients who progressed showed a more modest reduction in KRAS MAF (-55% and -26%)
- Patients with PR and stable disease (SD) tended to have lower on-treatment KRAS MAF than patients with early progressive disease (PD)

#### *Safety:*

- Onvansertib in combination with FOLFIRI/bevacizumab is safe and well tolerated with only 9% of all adverse events (AEs) being grade 3 or 4
- Grade 4 adverse events were attributed to the 5-FU bolus component of the combination regimen, which was eliminated in subsequent cycles of treatment per protocol and institutional guidelines
- The only G3/G4 AEs reported in  $\geq 2$  patients were neutropenia (n=8), which were managed by dose delay, growth factor therapy and/or discontinuation of the 5-FU bolus; no patients went off trial due to neutropenia
- No major or unexpected toxicities were attributed to onvansertib

The poster, *A phase Ib/II study of the polo-like kinase 1 (PLK1) inhibitor, onvansertib, in combination with FOLFIRI and bevacizumab for second-line treatment of patients with KRAS-mutated metastatic colorectal Cancer (mCRC)*, will be available on the "Scientific Presentations" section of the Cardiff Oncology website at <https://cardiffoncology.com/scientific-presentations/>.

### **About the Phase 1b/2 Trial of Onvansertib in KRAS-mutated mCRC**

This is a multi-center, open-label Phase 1b/2 trial of onvansertib in combination with standard-of-care FOLFIRI and Avastin® (bevacizumab) to evaluate the safety and preliminary efficacy of the combination regimen in the second-line treatment of patients with KRAS-mutated mCRC. The trial, *A Phase 1b/2 Study of Onvansertib (PCM-075) in Combination with FOLFIRI and Bevacizumab for Second-Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation*, will enroll up to 44 patients with a KRAS mutation and histologically confirmed metastatic and unresectable disease. In addition, eligible patients must have failed treatment with, or be intolerant to, FOLFOX (fluoropyrimidine and oxaliplatin) with or without bevacizumab. The trial is being conducted at six cancer centers across the U.S.: USC Norris Comprehensive Cancer Center, The Mayo Clinic (Arizona, Rochester and Jacksonville), Kansas University Medical Center (KUMC) and CARTI Cancer Center. For more information on the trial, please visit <https://clinicaltrials.gov/ct2/show/NCT03829410>.

### **About the Expanded Access Program (EAP) for Onvansertib in KRAS-mutated mCRC**

Sometimes called "compassionate use", expanded access is a potential pathway for a patient with a serious or life-threatening disease to gain access to an investigational drug for treatment outside of a clinical trial, particularly when no comparable or satisfactory alternative therapy options are available. The Cardiff Oncology EAP in KRAS-mutated mCRC is using the same combination treatment regimen (onvansertib 15 mg/m<sup>2</sup> + FOLFIRI/bevacizumab) and dosing schedule as the ongoing Phase 1b/2 clinical trial and is intended for patients that have progressed on prior therapy and do not meet the eligibility criteria for enrollment in the clinical trial. Requests for expanded access to onvansertib must be made by a U.S. licensed, treating physician. For more information on the expanded access program, please visit <https://clinicaltrials.gov/ct2/show/NCT04446793>.

### **About Cardiff Oncology, Inc.**

Cardiff Oncology Inc. is a clinical-stage biotechnology company with the singular mission of developing new treatment options for cancer patients in indications with the greatest medical need. Our goal is to overcome resistance, improve response to treatment and increase overall survival. We are developing onvansertib, a first-in-class, third-generation Polo-like Kinase 1 (PLK1) inhibitor, in combination with standard-of-care chemotherapy and targeted therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to enable assessment of patient response to treatment. We have three ongoing clinical programs that are demonstrating the safety and efficacy of onvansertib: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® (bevacizumab) in KRAS-mutated metastatic colorectal cancer (mCRC); a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in metastatic castration-resistant prostate cancer (mCRPC); and a Phase 2 study of onvansertib in combination with decitabine in relapsed or refractory acute myeloid leukemia (AML). For more information, please visit <https://www.cardiffoncology.com>.

### **Forward-Looking Statements**

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Cardiff Oncology's expectations, strategy, plans or intentions. These forward-looking statements are based on Cardiff Oncology's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, our need for additional financing; clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; our ability to develop tests, kits and systems and the success of those products; regulatory, financial and business risks related to our international expansion and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. There are no guarantees that any of our technology or products will be utilized or prove to be commercially successful. Additionally, there are no guarantees that future clinical trials will be completed or successful or that any precision medicine therapeutics will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in Cardiff Oncology's Form 10-K for the year ended December 31, 2019, and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Cardiff Oncology does not

undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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